K082325

7.0 510(K) SUMMARY

Submission Date: August 5, 2008

Submitter Information:

Company Name: Apexum Ltd.

APR 21 2009

Company Address: 6 Yoni Netanyahu St.
Or-Yehuda
Israel

Contact Person: Idan Tobis
General Manager
Apexum Ltd.
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idan@apexum.com

Device Information:

Trade Name: Apexum Ablator

Common Name: handpiece, belt and/or gear driven, dental, file, pulp canal, endodontic

Classification Name: handpiece, belt and/or gear driven, dental, file, pulp canal, endodontic

Device Class: Class I

Predicate Devices:

- K971603 Sterile Sureflex Files and Instruments
- K062856 TF Rotary Nickel Titanium File
- K004031 NT Swift; TITEC; Gates Glidden; Drills; Dental Power
- K920978 ULA (poliglecaprone 251) synthetic absor

Device Description:
The Apexum device consists of two parts, designed to be used sequentially: the Apexum NiTi Ablator and the Apexum PGA Ablator. It is designed to remove inflamed tissue during root canal treatment with a powered handpiece device.

Intended Use:

Removal of necrotic or inflamed tissues from the apical foramen and periapical region during root canal treatment.

Indications for Use:

Same as Intended Use

Comparison to Predicate Device:

The Apexum Ablator and the cited predicate devices have the same technological characteristics and indication for use. Some technical parameters differ between the Apexum Ablator and the predicate devices, but these differences are minor and do not affect safety or effectiveness. Safety and effectiveness evaluations based on animal and clinical studies indicate the device is substantially equivalent to the predicates cited.

Conclusion:

The results of the evaluation of the Apexum Ablator support the conclusion that it is as safe and effective as, and is substantially equivalent to, the cited predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Idan Tobis
General Manager
Apexum Limited
6 Yoni Netanyahu Street
Or-Yehuda 60376
ISRAEL

APR 21 2009

Re: K082325
Trade/Device Name: Apexum Ablator
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: I
Product Code: EKX
Dated: March 31, 2009
Received: April 2, 2009

Dear Mr. Tobis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

6.0 INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K082325

Device Name: Apexum Ablator

Indications for Use:

Removal of necrotic or inflamed tissue from the apical foramen and periapical region during root canal treatment.

Caution: Federal law restricts this device to sale by or on the order of a medical practitioner licensed by the law of the State in which he / she practices to use or order the use of the device.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ron Mulay for HSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082325